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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,220	05/22/2006	Ogari Pacheco	4705-0118PUS1	9789

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EXAMINER
HA, JULIE

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
05/14/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/565,220	PACHECO ET AL.	
	Examiner	Art Unit	
	Julie Ha	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-68* is/are pending in the application.

4a) Of the above claim(s) *49-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Election/Restriction filed on March 27, 2007 is acknowledged. Claims 1-36 were cancelled in the Preliminary amendment filed on January 20, 2006. Claims 37-68 are pending in this office action. Julie Ha is the Examiner on the record.

Restriction

1. Applicant's election with traverse of Group I (claims 37-48) drawn to a pharmaceutical composition of saquinavir and fatty acid, alcohols, and antioxidants and species election of oleic acid for fatty acid and ethanol for alcohol in the reply filed on March 27, 2007 is acknowledged. The traversal is on the ground(s) that the prior art used (Mitsuyasu et al) to break unity does not teach the instant application's special technical feature. The Applicants argue that Mitsuyasu et al report on a clinical trial comparing a hard gel capsule formulation of saquinavir to a soft gel capsule formulation of saquinavir. Further, the Applicants argue that the claimed invention is not directed to saquinavir per se, but rather to a composition of the drug and to methods for preparing and using the inventive formulation. This is not found persuasive because Alani et al (US Patent # 7141593) teach a improved pharmaceutical compositions comprising one or more solubilized HIV protease inhibiting compounds (saquinavir, see column 8, line 20) having improved solubility properties in a medium and/or long chain fatty acid, or mixtures thereof, a pharmaceutically acceptable alcohol, and water (see abstract), an antioxidant (see column 10, lines 25-30), and non-ionic surfactant (see column 11, lines

52-55). This breaks unity of invention because the special technical feature of instant claim 1 is not special, as disclosed by Alani patent.

The requirement is still deemed proper and is therefore made FINAL. Claims 49-68 are withdrawn from further consideration as being drawn to nonelected Inventions. Claims 37-48 are examined on the merits in this office action.

Rejection-35 U.S.C. 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 37-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipari et al (US Patent # 6232333).

4. The instant claims are drawn to a pharmaceutical composition for oral administration of saquinavir comprising: saquinavir or its pharmaceutical acceptable salts, a long chain fatty acid, at least an alcohol, a non-ionic surfactant, and a pharmaceutical acceptable antioxidant.

5. Lipari et al teach a liquid pharmaceutical composition comprising HIV protease providing improved oral bioavailability. The composition comprises a solution in a pharmaceutically acceptable organic solvent of a) the HIV protease inhibitor and, b) a surfactant, and can be encapsulated in either hard gelatin capsules or soft elastic capsules.(SEC) (see abstract) useful for inhibiting an HIV infection and treating AIDS in

humans (see column 32, lines 65-67). Furthermore, the reference teaches that the HIV protease inhibitors as individual compounds are the compound of formula III or V or saquinavir or nelfinavir or indinavir or VX-478 (see column 7, lines 8-11). This reads on claim 37(i). Additionally, the reference teaches a pharmaceutically acceptable organic solvent which comprises a pharmaceutically acceptable long chain fatty acid or a mixture of a pharmaceutically acceptable long chain fatty acid and a pharmaceutically acceptable alcohol, and a pharmaceutically acceptable surfactant (see column 7, lines 22-27). This reads on claims 37(ii), (iii), and (iv). Furthermore, the reference teaches that the solution composition can also comprise an antioxidant (ascorbic acid, BHA, BHT, vitamin E, vitamin E PEG 1000 succinate) for chemical stability (see column 8, lines 8-12). This reads on claim 37 (v) and 44. The reference lists the oleic acid as one of the fatty acid (see column 8, line 25), ethanol as one of the acceptable alcohol (see column 8, line 28) and non-ionic surfactants as derivatives of castor oil, Cremophor EL, Cremophor RH 40, and polyoxyethylene sorbitans (see column 8, lines 35-36). This reads on claims 37 and 41-43. The reference further teaches the concentration ranges of the components of the composition (see columns 9-12). The reference teaches that the solubilized HIV protease compound in the amount of from about 1% to about 50% (preferably 1 to 40%, 10 to 40% or 15 to 40%) by weight of the total solution (see column 9, lines 9-17), fatty acid in the amount of from about 20% to about 99% (see column 9, lines 20-21), alcohol in the amount of from about 0 to 15% (see column 9, lines 28-29), surfactant in the amount of from about 0 to 40%, encapsulated in a soft elastic gelatin or a hard gelatin capsule (see column 9, lines 31-36). Further, the

reference teaches the concentration ranges for ethanol (10%), oleic acid(52.5%), non-ionic surfactants (castor oil 10%) and antioxidant (0.1 to 0.8%) (see columns 10-12). This reads on claims 37-47. The reference further teaches that the parent drug under the curve (AUC) was calculated by the trapezoidal method over the time course of the study. The absolute bioavailability of each test composition was calculated by comparing the area under the curve after oral dosing to that obtained from a single intravenous dose (see column 32, lines 36-41). This reads on claim 48.

Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Julie Ha
Patent Examiner
AU 1654

5/9/07
ANISH GUPTA
PRIMARY EXAMINER